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| GRAY, PHILLIP A | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/582,914

Applicant(s)

ITOU ET AL.

Examiner

PHILLIP GRAY

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/22/2011
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to applicant's communication of 4/21/2011. Currently amended claims 1-27 are pending and rejected below. Rejection and response to arguments follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook (U.S. Patent 4,637,396) in view of Fina (U.S. Patent 4,911,163).

Cook discloses a balloon catheter with an outer catheter with an inner layer (22), outer layer (24) and reinforcing layer (23) and outer catheter hub (46) at the proximal end, an inner catheter (13) with a hard proximal part (40) softer distal part (18), and inner catheter hub (55), and second soft tip (17) on the proximal end (see figure 1-3) wherein said outer catheter hub and inner hub are adapted to be fixed to each other as not to rotate and when engaged the inner catheter protrudes from the outer catheter with the distance no more than 10 mm (see figure 1). Concerning claim 3, 8, and 18-20 note lower portion of figure 2. Concerning claim 4 and 9-10 note portion near 28-29. Concerning claim 5 note figure 1. Concerning claim 6 and 11-14 see layer 19.

Concerning the claim language of the outer catheter hub and said inner catheter hub are disengaged from each other so that said inner catheter is removable from said outer catheter, it is examiners position that the prior art reference would have the ability to disengage from each other, if joints at 53 or 46 in figure 5 were unscrewed or displaced then the outer and inner catheter/hubs would be removable and disengaged from one another. Further it is examiners position that figure 5 and figure 1 shown the device when the outer and inner hubs are engaged with each other and the two catheters do not move relative to one another.

Cook discloses the claimed invention except for the locking and removable inner catheter. Fina teaches that it is known to use a removable inner catheter which also locks as set forth in paragraphs at column 3-6 discussing how catheter 2 relates to catheter 8, to provide two catheters that may function jointly or independently of one another. It would have been obvious to one having ordinary skill in the art at the time

the invention was made to modify the system as taught by Cook with a removable inner catheter as taught by Fina, since such a modification would provide the System with a removable inner catheter for providing two catheters that may function jointly or independently of one another.

Concerning the claim language of "an inner surface of said outer catheter and outer surface of said inner catheter are not fixedly secured to one another such that said inner catheter is removable from said outer catheter when said outer catheter hub and said inner catheter hub are disengaged from each other, .." It is examiners position that this would be present in the Fina reference. Taking note, it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Newin v. Erlichman*, 168 USPQ 177 (BdPatApp&Int 1969). When making two tubes separate or separable from one another you are not going make them "fixedly secure" to one another. Further it has been held that the provision of adjustability, where needed, involves only routine skill in the art. *In re Stevens*, 1010 USPQ 284 (CCPA 1954). constructing a formerly integral structure in various element involves only routine skill in the art. One would wish to construct something in various separate pieces (inner and outer not fixedly attached) in order to replace individual element structures or customize particular pieces, or to provide a modular cheaper to manufacture design.

Claims 7, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fina. Cook in view of Fina discloses the claimed invention except for

the .90 ratio of the outside to inside catheter diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct a .90 ratio of the outside to inside catheter diameters., since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Concerning claim 21 it is examiners position that Cook teaches this (see figures 1 and 5 and note how each of the elements of cook are detachable and are removed from the proximal opening when two hubs are disengaged (i.e. near 27 or 55), also Fina teaches this same function of when the hubs are disengaged the inner catheter may be removed proximally through the outer catheter (see figures 3 and 2 and note hub connection near 19 for example). In the alternative, further more it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Therefore it is examiners position that making a inner catheter removable from an outer catheter where the inner catheter is removed from the proximal end is well known in the art as a way to remove one catheter from the other and therefore is an obvious modification

Further see marked up figure 2 of Fina below.

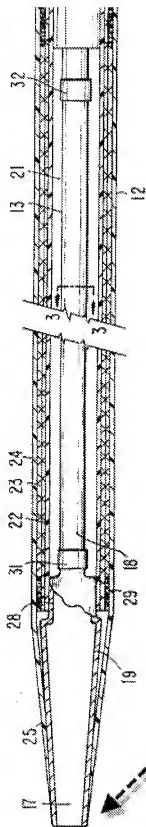


Fig.2

Concerning the newly amended claims 22-27 see rejection above of prior identified structures as in the preceding claims. Concerning claim 22 and the 10mm protruding see figure 1 and further a change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Concerning claim 23, and 26 and the round tip having a length of about 0.5 to 3mm, it is examiner position that the prior art does disclose this however if not it would have been an obvious modification since a change in size is generally recognized as being within the level of ordinary skill in the art. Concerning claim 24 and 27, It is examiners position that the outer catheter of the prior art Cook is continuous and integral, as in figures 1-2. Concerning claim 25 see previous rejection of claimed structures above, as in claim 1 for example.

Concerning the amended claim language as in claims 1 and 25 of "...wherein said inner catheter is withdrawn from said outer catheter after the catheter assembly has been placed at a target site, and a procedure catheter is then inserted into said outer catheter which remains in the target site...", examiner is reading this as an intended use or functional limitation. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitation of the claim. Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed

apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. It is examiner's position that the prior art of record and any obvious modifications thereof are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper.

Response to Arguments

Applicant's arguments filed 4/21/2011 have been fully considered but they are not persuasive.

Applicants argue that the prior art of record (Cook in view of Fina) fails to teach or disclose "...wherein said inner catheter is withdrawn from said outer catheter after the catheter assembly has been placed at a target site, and a procedure catheter is then inserted into said outer catheter which remains in the target site...", examiner is reading this as an intended use or functional limitation. It is examiners position that this would be present in Cook and Fina references and the prior art when taken as a whole, and all obvious modifications thereof. As discussed in the rejection above it is examiners position that the prior art when taken as a whole and any obvious modifications thereof would be fully capable of these claimed functions and intended uses. The catheters would be detachable from one another and when the unit is together in a patient may be

removed independently from another and an additional catheter could be inserted. There are no structures in the prior art which would prevent this intended use or function.

It is recommended applicant amend the claims to distinguish over the prior art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHILLIP GRAY whose telephone number is (571)272-

7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/
Examiner, Art Unit 3767

/Theodore J Stigell/
Primary Examiner, Art Unit 3763